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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,039	07/18/2003	Subhashis Banerjee	BBI-8188RCE	1401
959 7590 02/26/2009 LAHIVE & COCKFIELD, LLP FLOOR 30, SUITE 3000 ONE POST OFFICE SQUARE BOSTON, MA 02109				
EXAMINER BLANCHARD, DAVID J				
ART UNIT		PAPER NUMBER		
1643				
MAIL DATE		DELIVERY MODE		
02/26/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/623,039

**Applicant(s)**

BANERJEE ET AL.

**Examiner**

David J. Blanchard

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 12, 18, 22, 23 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 12, 18, 22, 23 and 26-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09 December 2008 has been entered.
2. Claims 2, 5-11, 13-17, 19-21 and 24-25 have been cancelled.  
Claims 1, 3, 12, 18, 22 and 26-38 have been amended.  
Claims 49-56 have been added.
3. Claims 1, 3-4, 12, 18, 22-23 and 26-56 are pending and under consideration to the extent that the spondyloarthropathy is psoriatic arthritis, i.e., applicants' elected species.
4. This Office Action contains New Grounds of Rejections

### ***Objections/Rejections Withdrawn***

5. The objection to the title of the invention as not descriptive or clearly indicative of the invention to which the claims are directed is withdrawn in view of the newly submitted title filed 12/9/08.
6. The provisional rejection of claims 2, 6, 14-15 and 20 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1, 3-10, 16-21, 78-79, 81, 84, 86-88, 95, 97-98 and newly added claims 100-104 of copending Application No. 10/163,657 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) is withdrawn in view of the cancellation of claims 2, 6, 14-15 and 20.

***Objections/Rejections Maintained and New Grounds of Rejections***

7. The objection to the specification as disclosing various non-provisional US Application numbers whose status has changed and require updating is maintained.

Applicant's remarks filed 12/9/2008 are acknowledged, however, in view that USSNs 10/163,657 and 10/622,932 are pending and may require updating during the pendency of the instant application, the objection is being maintained for convenience.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-48 and now applied to newly added claims 49-56 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001, cited on PTO-892 mailed 9/24/07) in view of Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980, cited on PTO-892 mailed 9/24/07) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic*, 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 12/9/2008 argues the individual teachings of Ogilvie et al, Salfeld et al [a] and Keystone et al, stating that Ogilvie et al doesn't teach or suggest that a human anti-TNF $\alpha$  antibody could be used in a biweekly, subcutaneous dosing regimen involving the administration of the antibody in a unit dosage form that is independent of body weight, wherein the same dosage amount is administered throughout the course of treatment in accordance with the amended claims, and Ogilvie et al describes a weight-based dosing scheme. Applicant states that Salfeld et al [a] does not teach a dosage of a human anti-TNF $\alpha$  or antigen-binding fragment thereof comprising a dosage of 10-150 mg that is independent of body weight and given the success of Ogilvie in treating PsA patient using infliximab at 5 mg/kg at wks 0, 2 and 6, one of ordinary skill in the art would not conclude that administration of a human anti-TNF $\alpha$  antibody at a dosage comprising 10-150 mg independent of body weight would be efficacious in treating PsA either alone or in combination with ibuprofen (Smith et al). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Additionally, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it

that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant also states that Keystone et al is limited to the treatment of rheumatoid arthritis which is distinct from psoriatic arthritis and there is nothing in the combined teachings of the references that suggests that the regimen of Keystone et al would successfully treat psoriatic arthritis, since dosing regimens can vary significantly by disease in terms of both dosage and frequency. Applicant submits that the references must be viewed without the benefit of impermissible hindsight. At pg. 14 of the response, Applicant presents different dosing regimens for the chimeric TNF $\alpha$  antibody, infliximab, used for treatment of psoriasis, rheumatoid arthritis and ankylosing spondylitis to support the position that the same agent to treat more than one disorder does not necessarily have the same dosing regimen. Applicant concludes that one of average skill in the art could not have reasonably predicted that a biweekly, subcutaneous dosage regimen of a human TNF $\alpha$  antibody, e.g., D2E7, to patients also receiving ibuprofen as described by Keystone et al for treating rheumatoid arthritis would be successful in treating psoriasis based on Ogilvie et al's observation that symptoms of psoriatic arthritis improved following administration of infliximab as a weight-based dosage of 5 mg/kg at weeks 0, 2 and 6. Applicants' arguments have been fully considered but are not found persuasive. While Keystone et al do teach the subcutaneous biweekly administration of the fully human anti-TNF $\alpha$  antibody D2E7 as taught by Salfeld et al [a] at 20 mg, 40 mg and 80 mg for the treatment of *rheumatoid arthritis*, the teachings of Keystone et al indicate that the administered D2E7 antibody was well tolerated and therapeutically effective, particularly at 40 mg every other week. Thus, while one of ordinary skill in the art would recognize that the optimal dosing regimen for the D2E7 antibody may vary for the treatment of other TNF $\alpha$ -mediated disorders, such as psoriatic arthritis as taught by Ogilvie et al, given the success of D2E7 administered subcutaneously at 20 mg, 40 mg and 80 mg every other week (i.e.,

biweekly), one of ordinary skill in the art would have been motivated to at least administer the D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week for the treatment of psoriatic arthritis. "[A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1397. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Additionally, one of ordinary skill in the art would have been motivated to look beyond the teachings of Ogilvie et al and administer the fully human D2E7 antibody or antigen-binding fragments thereof subcutaneously at 20 mg, 40 mg or 80 mg every other week for the treatment of psoriatic arthritis, since chimeric and humanized antibodies retain some murine sequence and hence, may still elicit an unwanted immune reaction in human patients according to Salfeld et al [a]. Applicant is reminded that obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). In the instant case, one of ordinary skill in the art would have a reasonable expectation of success in view of the teachings of Ogilvie et al providing evidence that the administration of an anti-TNF $\alpha$  antibody is a clinically effective treatment for psoriasis and the fully human anti-TNF $\alpha$  antibody D2E7 was well tolerated and therapeutically effective in patients according to Keystone et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

10. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-48 and now applied to newly added claims 49-56 under 35 U.S.C. 103(a) as being unpatentable over Ogilvie et al

(British Journal of Dermatology, 144(3):587-589, March 2001) in view of Salfeld et al [b] (U.S. Patent 6,509,015 B1, 2/9/1996, IDS reference A2 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001*, IDS reference C64 filed 5/13/08).

The applied reference (Salfeld et al [b]) has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The response filed 12/9/08 argues as above and the examiner's remarks above apply here as well and are incorporated herein by reference. It is noted that the instant rejection differs only in the use of Salfeld et al [b], however, Salfeld et al [a] and [b] are equivalent teachings.

Therefore, as discussed supra the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29



USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. The rejection of claims 1, 3-4, 12, 18, 22-23, 26-48 and now applied to newly added claims 49-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 36-39 and 69 of U.S. Patent No. 6,509,015 B1 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, 2001*, IDS reference C64 filed 5/13/08) is maintained.

The response filed 12/9/2008 argues as above, i.e., the combined teachings of Ogilvie et al, Salfeld et al and Keystone et al fail to provide a reasonable expectation of success for the treatment of psoriatic arthritis with biweekly, subcutaneous dosage regimen of human anti-TNF $\alpha$  antibody as presently claimed. Applicants' arguments have been fully considered but are not found persuasive for the reasons set forth above and incorporated herein by reference, and in view that no terminal disclaimer has been filed.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 6,509,015

B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

13. The provisional rejection of claims 1, 3-4, 12, 18, 22-23, 26-48 and now applied to newly added claims 49-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-5, 8-11, 14, 38-39, 49-50, 52-53 and 55-57 of copending Application No. 11/435,844 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic*, 2001, IDS reference C64 filed 5/13/08) is maintained.

The response filed 12/9/2008 notes that the rejection is provisional in nature and submits that this rejection will be further addressed when the claims are otherwise in condition for allowance. Applicants' remarks are acknowledged, however, the claims are not currently in condition for allowance and not terminal disclaimer has been filed and as such, the rejection is maintained.

Applicant is reminded that the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common

ownership (see MPEP Chapter 2300). Commonly assigned copending Application No. 11/435,844, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

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14. The provisional rejection of claims 1, 3-4, 12, 18, 22-23, 26-48 and now applied to newly added claims 49-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 19, 56, 66, 77 and 87 of copending Application No. 11/233,252 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) and Keystone et al ("The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)", *Presented at the Annual Meeting of the Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic*, 2001, IDS reference C64 filed 5/13/08) is maintained.

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15. The provisional rejection of claims 1, 3-4, 12, 18, 22-23 and now applied to claims 26-56 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 1, 4-10, 16-21, 78-79, 81, 84, 86-88, 95, 97-98 and 100-104 of copending Application No. 10/163,657 in view of Ogilvie et al (British Journal of Dermatology, 144(3):587-589, March 2001) and Salfeld et al [a] (WO 97/29131, publication date 8/14/1997, IDS reference A4 filed 4/6/04) and Smith et al (Arthritis Rheum. 23(8):961-962, August 1980) is maintained.

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/  
Primary Examiner, A.U. 1643